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Display Date NOV -8 2004
Publication Date
Certifier

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0480]

The Minor Use and Minor Species Animal Health Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development and is requesting comments on the implementation of the newly enacted MUMS Animal Health Act. This notice is intended to provide the public with contact information for the new MUMS office as well as to provide a venue for public comment.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Andrew Beaulieu, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301–827–2945, *abeaulie@cvm.fda.gov.* Alternatively, you may contact Margaret Oeller, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301–827–3067, *moeller@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The MUMS Animal Health Act became law on August 2, 2004 (Public Law 108–282). Several elements of the law became immediately effective on that date. These include the provisions for designation of MUMS drugs under section 573 and for conditional approval of MUMS drugs under section 571. The indexing provisions under section 572 of the law will only become effective upon publication of final implementing regulations. As mandated by the MUMS law, FDA has established the new Office of MUMS Animal Drug Development in the Center for Veterinary Medicine (CVM). FDA is requesting comments on any aspect of implementation of the MUMS legislation (see section II of this document). Requests for further information should be directed to the Office of MUMS Animal Drug Development (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/2/04
November 2, 2004.

cv04102

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S